

EXHIBIT 12

	COVIDIEN	Title: HZQS - Identification, Investigation, and Reports of Controlled Substances Suspicious Orders	Effective Date: 10/18/12
Procedure			Supersedes Date: 09/20/12
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1. PURPOSE

This procedure outlines the Identification and Investigation of Suspicious Orders component of the Mallinckrodt Suspicious Order Monitoring Program and the reporting of any Suspicious Orders to DEA.

2. SCOPE

It is Mallinckrodt's corporate policy that orders for controlled substances which have been determined to be Suspicious Orders (order of an Suspicious size, deviating from a normal pattern, or of an Suspicious frequency) will be reported to DEA upon discovery in accordance with 21 C.F.R. § 1301.74(b). Mallinckrodt will hold Suspicious Orders and not ship to the customer until Mallinckrodt conducts an independent analysis to determine whether the controlled substances are likely to be diverted from legitimate channels.

3. REFERENCES

- 3.1 **(HZQS-DMS precedes all Hazelwood documents in the DMS system)**
- 3.2 21 C.F.R. § 1301.74(b)
- 3.3 Suspicious Order Report

4. DEFINITIONS

- 4.1 **Suspicious Order:** An order received by Mallinckrodt directly from a customer for a Schedule II - V Controlled Substance product which exceeds the internal limit set by the application of the two-tiered system of specifically created algorithms defined in this policy. Suspicious Orders will be reported to DEA upon discovery in accordance with 21 C.F.R. § 1301.74(b).
- 4.2 **Tier 1:** A monthly limit set annually for large volume wholesalers' or distributors' orders of Oxycodone 15 mg and 30mg SKUs. These products have been identified by DEA as particularly subject to diversion and abuse.
- 4.3 **Tier 2:** A standard algorithm with respect to volume which sets a monthly limit at: (a) [REDACTED]
[REDACTED]
- 4.4 The **SOM Leadership Team** is comprised of:
 - 4.4.1 Associate General Counsel, Don Lohman
 - 4.4.2 Director of Global Security, John Gillies
 - 4.4.3 Director of Government Reporting Compliance, Gail Tetzlaff
 - 4.4.4 Sr. Manager, Controlled Substances Compliance Group, Karen Harper

5. RESPONSIBILITIES

- 5.1 This policy is owned by the Manager of Controlled Substances Compliance ("MCSC") within the Legal Department and is applicable to the following:
 - 5.1.1 Suspicious Order Monitoring Analyst and designees
 - 5.1.2 Manager, Controlled Substances Compliance (MSCS)
 - 5.1.3 Director of Government Reporting Compliance (DGRC)
 - 5.1.4 Suspicious Order Monitoring (SOM) Leadership Team
- 5.2 The SOM Analyst or designee will create and maintain Suspicious Order investigation files for all documentation related to such investigations. The files will be maintained in a location within the Legal Department.

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6. PROCEDURE

6.1 Establishing and Reviewing Algorithms

6.1.1 The SOM Leadership Team is responsible for identifying which Tier applies to which controlled substances product orders and from which customers. These algorithms will be established by the SOM Leadership Team based upon a detailed analysis of order history, quota statistics, IMS data, chargebacks and any other data deemed relevant by the SOM Leadership Team. Algorithms will be subject to annual review and revised for the upcoming year, if necessary. The SOM Leadership Team, at its discretion, may retain the services of a DEA consultant to assist in the establishment and review of the algorithms.

6.1.1.1 Algorithms or limits may be adjusted at the request of the Commercial Group. Adjustments will be approved by the SOM Leadership Team if the Commercial Group provides satisfactory justification for the adjustment, in writing.

6.1.1.2 The SOM Leadership Team approval of algorithm adjustment will be documented.

6.2 Suspicious Order Reports

6.2.1 The algorithms will be programmed into the order system by Information Services as directed by the SOM Leadership Team to automatically prepare a twice daily Suspicious Order Report which will be reviewed and investigated by the SOM Analyst or designee. All internal and external communications and the resolutions of all investigations shall be documented by the SOM Analyst or designee and placed in the Suspicious Order investigation files.

6.3 Ship-Hold

6.3.1 A ship-hold automatically will be placed on each order on the Suspicious Order Report until the final determination is made, in writing, with respect to the order by the SOM Leadership Team or designee.

6.4 Investigation of Tier 1 Suspicious Orders

6.4.1 The SOM Analyst or designee will prepare a written report of the Suspicious Orders upon discovery and document the reporting of the Suspicious Orders to DEA. The files will be maintained in a location within the Legal Department.

6.4.2 The SOM Analyst or designee will conduct the first level of investigation by obtaining more detailed reports concerning the Suspicious Order from the order system and further analyzing the Suspicious Order within the context of that information.

6.4.3 The SOM Analyst or designee, at his/her discretion, may confer (but is not required to confer) with the Commercial Group representative (Product Manager for the product in the Suspicious Order and/or the National Account Manager) responsible for the customer placing the order to obtain additional information concerning the Suspicious Order.

6.4.4 After completion of the initial investigation of the Suspicious Order, the SOM Analyst or designee will forward notification that the Suspicious Order report is ready for review to the DGRC and MCSC.

6.4.5 The DGRC or MCSC will review the report, document the recommended disposition of the order within the report and respond that the order shall be released or request additional investigation.

6.4.6 If additional investigation is required, the MCSC or designee may confer (but is not required to confer) with his/her SOM counterpart at the customer who placed the order to obtain additional information concerning the Suspicious Order. The MCSC will

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document the information and, if necessary, confer with the Commercial Group to confirm the plausibility of the explanation.

6.4.7 The MCSC or designee will then present the results of his/her investigation directly to the remainder of the SOM Leadership Team and make a recommendation to: a) reject and cancel the Suspicious Order, or b) authorize release of the order for shipment

6.4.8 The SOM Leadership Team will accept the recommendation to a) reject and cancel the Suspicious Order or b) authorize release of the order for shipment

6.4.9 If the recommendation to reject and cancel the Suspicious Order is accepted by the SOM Leadership Team,

6.4.9.1 Customer Service will cancel the Suspicious Order as directed by the SOM Leadership Team.

6.4.9.2 The MCSC will notify the VP of Commercial Operations, the Product Manager for the product in the Suspicious Order and the National Account Manager responsible for the customer placing the order of the decision to reject and cancel the order.

6.4.9.3 The MCSC, at his/her discretion, may notify his/her SOM counterpart at the customer of the SOM Leadership Team's decision to reject and cancel the order.

6.5 Investigation of Tier 2 Suspicious Orders

6.5.1 The SOM Analyst or designee will prepare a written report of the Suspicious Orders upon discovery and document the reporting of the Suspicious Orders to DEA. The files will be maintained in a location within the Legal Department.

6.5.2 The SOM Analyst or designee will conduct the first level of investigation by obtaining more detailed reports concerning the Suspicious Order from the order system and further analyzing the Suspicious Order within the context of that information.

6.5.3 The SOM Analyst or designee, at his/her discretion, may confer (but is not required to confer) with the Commercial Group representative (Product Manager for the product in the Suspicious Order and/or the National Account Manager) responsible for the customer placing the order to obtain additional information concerning the Suspicious Order.

6.5.4 After completion of the initial investigation of the Suspicious Order, the SOM Analyst or designee will forward notification that the Suspicious Order report is ready for review to the DGRC and MCSC.

6.5.5 The DGRC or MCSC will review the report, document the recommended disposition of the order within the report and respond that the order shall be released or request additional investigation.

6.5.6 If additional investigation is required, the MCSC or designee may confer (but is not required to confer) with his/her SOM counterpart at the customer who placed the order to obtain additional information concerning the Suspicious Order. The MCSC will document the information and, if necessary, confer with the Commercial Group to confirm the plausibility of the explanation.

6.5.7 The MCSC or designee will then present the results of his/her investigation directly to the remainder of the SOM Leadership Team and make a recommendation to: a) reject and cancel the Suspicious Order, or b) authorize release of the order for shipment

6.5.8 The SOM Leadership Team will accept the recommendation to a) reject and cancel the Suspicious Order or b) authorize release of the order for shipment

6.5.9 If the recommendation to reject and cancel the Suspicious Order is accepted by the SOM Leadership Team,

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- 6.5.9.1 Customer Service will cancel the Suspicious Order as directed by the SOM Leadership Team.
- 6.5.9.2 The MCSC will notify the VP of Commercial Operations, the Product Manager for the product in the Suspicious Order and the National Account Manager responsible for the customer placing the order of the decision to reject and cancel the order.
- 6.5.9.3 The MCSC, at his/her discretion, may notify his/her SOM counterpart at the customer of the SOM Leadership Team's decision to reject and cancel the order.

7. ATTACHMENTS

7.1 NONE

8. RELATED FORMS

8.1 NONE

9. REVISION HISTORY

Revision Number	Effective Date	Section	Revision
1	10/18/12	6.4.9 and 6.5.9	<p>If the SOM Leadership Team determines the explanation for the Suspicious Order is not sufficient, the SOM Leadership Team will: (1) reject the Suspicious Order and (2) direct Customer Service Representative to cancel the Suspicious Order.</p> <p>Customer Service will cancel the Suspicious Order as directed by the SOM Leadership Team</p> <p>The MCSC will notify the VP of Commercial Operations, the Product Manager for the product in the Suspicious Order and the National Account Manager responsible for the customer placing the order of the decision to reject the order</p> <p>The MCSC, at his/her discretion, May notify his/her SOM counterpart at the customer of the SOM Leadership Team's decision to reject the order</p> <p>All references to Unusual Order Report (UOR) changed to Suspicious Order Report (SOR)</p>
NEW	09/20/12	All	New document.

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